

Benjamin A. Nix (SBN 138258)  
Payne & Fears LLP  
Jamboree Center  
4 Park Plaza, Suite 1100  
Irvine, CA 92614  
Tel.: 949-851-1100  
Fax: 949-851-1212  
Email: ban@paynefears.com

Kirby D. Behre (Admitted *pro hac vice*)  
Nina C. Gupta (Admitted *pro hac vice*)  
Dwight B.N. Pope (Admitted *pro hac vice*)  
Miller & Chevalier Chartered  
900 Sixteenth St. NW  
Washington, DC 20006  
Tel.: 202-626-5800  
Fax.: 202-626-5801  
Email: kbehre@milchev.com  
Email: ngupta@milchev.com  
Email: dpope@milchev.com

Marc C. Sanchez (Admitted *pro hac vice*)  
Contract In-House Counsel & Consultants LLC (d/b/a FDA Atty)  
1717 Pennsylvania Ave. NW, Suite 1025  
Washington, DC 20006  
Tel.: 202-765-4491  
Fax.: None  
Email: msanchez@fdaatty.com

*Attorneys for Defendant*  
**HOTAN BAROUGH**

UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

INNOVATIVE BIODEFENSE, INC. ET  
AL.,

Defendants.

Case No. 8:18-cv-00996-DOC-JDE

**DEFENDANT HOTAN BAROUGH'S  
ANSWER AND AFFIRMATIVE  
DEFENSES TO THE AMENDED  
COMPLAINT**

Judge Carter

## PRELIMINARY STATEMENT

Defendant Hotan Barough owns a small product fulfillment business and operates out of his home. His business is called Zylast Direct, which fulfills orders for just one product line: Zylast, marketed by Defendant Innovative BioDefense, Inc. (“IBD”). The Zylast products are hand sanitizers (also known as topical antiseptics). Mr. Barough’s company fulfills all orders purchased on Amazon, and he fulfills orders placed on Zylast Direct’s website, [www.zylastdirect.com](http://www.zylastdirect.com). Mr. Barough is neither an employee nor agent of IBD.

The Government has belatedly sued Mr. Barough for statements made about the Zylast products on Zylast Direct's website. Many of those statements have not been made for several years. The FDA never notified Mr. Barough about the FDA's concerns about the statements in the Amended Complaint, nor requested that he remove those statements. Since he was served with the Amended Complaint, Mr. Barough has removed all objectionable statements referenced in the Amended Complaint from the Zylast Direct website.

1. This paragraph consists of conclusions of law to which no response is required. The law cited speaks for itself.

## JURISDICTION AND VENUE

3. This paragraph consists of conclusions of law and legal arguments to which no response is required. The law cited speaks for itself.

## DEFENDANTS

1           5. Defendant Barough lacks knowledge or information sufficient to form a  
2 belief about the truth of the allegations in the paragraph.

3           6. Defendant Barough lacks knowledge or information sufficient to form a  
4 belief about the truth of the allegations in the paragraph.

5           7. Defendant Barough admits: (a) that he is an individual doing business as  
6 Zylast Direct, a California sole proprietorship; (b) that he maintains the website  
7 [www.zylastdirect.com](http://www.zylastdirect.com), through which Zylast products are sold; (c) that he ships orders  
8 of Zylast products purchased through [www.zylastdirect.com](http://www.zylastdirect.com); and (d) that he has  
9 offered Zylast products for sale and accepted orders for such products through  
10 Amazon.com. Mr. Barough denies the remaining allegations in the paragraph.

11                           **DEFENDANT'S OPERATIONS**

12           8. Defendant Barough admits that he has shipped Zylast products to  
13 customers outside of California, but denies the remaining allegations in the paragraph.

14           9. Plaintiff's allegations regarding the website referenced in the paragraph  
15 fail to specify the date or date range during which the website appeared as alleged.  
16 Nonetheless, Defendant Barough lacks knowledge or information sufficient to form a  
17 belief about the truth of the allegations in the paragraph.

18           10. Defendant Barough lacks knowledge or information sufficient to form a  
19 belief about the truth of the allegations in the paragraph.

20           11. Plaintiff's allegations regarding the websites referenced in the paragraph  
21 fail to specify the date or date range during which the websites appeared as alleged.  
22 Nonetheless, Defendant Barough admits that customers can purchase Zylast products  
23 at [www.zylastdirect.com](http://www.zylastdirect.com). Defendant Barough denies that [www.zylast.com](http://www.zylast.com) and  
24 [www.zylastdirect.com](http://www.zylastdirect.com) employ similar designs and contain similar information.  
25 Defendant Barough lacks knowledge or information sufficient to form a belief about  
26 the truth of the remaining allegations in the paragraph.

27           12. Plaintiff's allegations regarding the websites referenced in the paragraph  
28 fail to specify the date or date range during which the websites appeared as alleged.

1 Nonetheless, Defendant Barough denies: (a) that [www.zylastdirect.com](http://www.zylastdirect.com) currently  
2 includes hyperlinks to the Facebook page <http://www.facebook.com/ZylastXP>, and (b)  
3 that there is a hyperlink on [www.zylastdirect.com](http://www.zylastdirect.com) to the Twitter feed  
4 <http://twitter.com/ZylastXP>. Defendant Barough lacks knowledge or information  
5 sufficient to form a belief about the truth of the remaining allegations in the paragraph.

6 **REQUIREMENT OF THE ACT**

7 13. This paragraph consists of conclusions of law and legal arguments to  
8 which no response is required. The law cited speaks for itself.

9 14. This paragraph consists of conclusions of law and legal arguments to  
10 which no response is required. The law cited speaks for itself.

11 15. This paragraph consists of conclusions of law and legal arguments to  
12 which no response is required. The law cited speaks for itself.

13 16. This paragraph consists of conclusions of law and legal arguments to  
14 which no response is required. The law cited speaks for itself.

15 17. This paragraph consists of conclusions of law and legal arguments to  
16 which no response is required. The law cited speaks for itself.

17 18. This paragraph consists of conclusions of law and legal arguments to  
18 which no response is required. The law cited speaks for itself.

19 **DEFENDANTS DISTRIBUTE UNAPPROVED NEW DRUGS**

20 **IN VIOLATION OF THE ACT**

21 19. This paragraph consists of conclusions of law and legal arguments to  
22 which no response is required. Furthermore, Plaintiff's allegations regarding the  
23 websites referenced in the paragraph fail to specify the date or date range during which  
24 the websites appeared as alleged. Nonetheless, Defendant Barough denies that—  
25 according to [www.zylastdirect.com](http://www.zylastdirect.com) and the Twitter page referenced in Paragraph 12—  
26 Zylast products are intended to be used for the purposes listed in this this paragraph.  
27 No such statements currently appear on [www.zylastdirect.com](http://www.zylastdirect.com) and the Twitter page  
28 referenced in Paragraph 12 has been discontinued. Defendant Barough lacks

1 knowledge or information sufficient to form a belief about the truth of the remaining  
2 allegations in the paragraph.

3 20. Defendant Barough lacks knowledge or information sufficient to form a  
4 belief about the truth of the allegations in the paragraph.

5 21. Defendant Barough denies the allegations in the paragraph. None of the  
6 statements listed in this paragraph are currently on [www.zylastdirect.com](http://www.zylastdirect.com).

7 22. Defendant Barough lacks knowledge or information sufficient to form a  
8 belief about the truth of the allegations in the paragraph.

9 23. Defendant Barough lacks knowledge or information sufficient to form a  
10 belief about the truth of the allegations in the paragraph.

11 24. This paragraph consists of conclusions of law and legal arguments to  
12 which no response is required. Defendant Barough lacks knowledge or information  
13 sufficient to form a belief about the truth of the remaining allegations in the paragraph.

14 25. This paragraph consists of conclusions of law and legal arguments to  
15 which no response is required. Defendant Barough lacks knowledge or information  
16 sufficient to form a belief about the truth of the remaining allegations in the paragraph.

### 17 **INTERSTATE COMMERCE**

18 26. Defendant Barough admits that he has shipped Zylast products outside of  
19 California. Defendant Barough lacks knowledge or information sufficient to form a  
20 belief about the truth of whether the FDA has documented the shipment of Zylast  
21 products from California to Arizona. The remaining allegations in this paragraph  
22 consist of conclusions of law and legal arguments to which no response is required.

### 23 **HISTORY OF VIOLATIONS**

24 27. This paragraph consists of conclusions of law and legal arguments to  
25 which no response is required. Nonetheless, Defendant Barough denies the allegations  
26 in the paragraph. Until Plaintiff filed the Amended Complaint, the FDA never  
27 informed Mr. Barough about the statements on his website the FDA alleges are  
28

improper. The FDA neither issued a Warning Letter to Mr. Barough nor sought his voluntary agreement to remove statements with which the FDA had concerns.

28. Defendant Barough lacks knowledge or information sufficient to form a belief about the truth of the allegations in the paragraph.

29. Defendant Barough lacks knowledge or information sufficient to form a belief about the truth of the allegations in the paragraph.

30. Defendant Barough lacks knowledge or information sufficient to form a belief about the truth of the allegations in the paragraph.

31. Defendant Barough lacks knowledge or information sufficient to form a belief about the truth of the allegations in the paragraph.

32. This paragraph consists of conclusions of law and legal arguments to which no response is required. Nonetheless, Defendant Barough denies the allegations in the paragraph.

#### **PLAINTIFF'S PRAYER FOR RELIEF**

I. Defendant Barough denies that Plaintiff is entitled to such relief.

II. Defendant Barough denies that Plaintiff is entitled to such relief.

III. Defendant Barough denies that Plaintiff is entitled to such relief.

IV. Defendant Barough denies that Plaintiff is entitled to such relief.

#### **AFFIRMATIVE DEFENSES**

Further responding to the Amended Complaint and as additional defenses thereto, Defendant Barough asserts the following affirmative defenses, without admitting any allegations of the Amended Complaint not previously admitted, and without admitting that the Defendant Barough bears the burden of proof or burden of persuasion on any matter set forth herein.

#### **FIRST AFFIRMATIVE DEFENSE**

The relief sought in the Amended Complaint is barred by the doctrine of laches, in that Plaintiff has unreasonably delayed efforts to enforce its rights, if any, despite its awareness of Defendant Barough's existence and actions. Plaintiff admitted in its

1 Amended Complaint that the FDA sent a Warning Letter to Defendants IBD and  
2 Colette Cozean on June 30, 2015, Am. Compl. ¶ 28, which did not include Mr.  
3 Barough, but did not file suit against Defendants IBD and Dr. Cozean until June 6,  
4 2018. *See* Compl. Moreover, the FDA never informed Defendant Barough either by  
5 Warning Letter or otherwise about his alleged violations until the filing of the  
6 Amended Complaint on August 28, 2018, belatedly adding him as a Defendant. *See*  
7 Am. Compl.

### 8 **SECOND AFFIRMATIVE DEFENSE**

9 The relief sought in the Amended Complaint is barred by the doctrine of unclean  
10 hands, in that Plaintiff has acted inequitably by selectively enforcing the Act and FDA  
11 regulations against Defendants, and not other persons or entities that sell OTC drug  
12 products and make similar claims about their products. Plaintiff's conduct has  
13 unjustifiably injured Defendant.

### 14 **THIRD AFFIRMATIVE DEFENSE**

15 Defendant Barough has acted reasonably and in good faith in an effort to comply  
16 with all applicable FDA regulations. Notably, Defendant Barough never received  
17 notice of his alleged violations until he was served with the Amended Complaint.  
18 After the Court's order on the Motion to Dismiss (ECF No. 60), Hotan Barough  
19 removed all objectionable statements identified in the Amended Complaint from  
20 [www.zylastdirect.com](http://www.zylastdirect.com).

### 21 **FOURTH AFFIRMATIVE DEFENSE**

22 It is undisputed that there is no public health danger presented by the Zylast  
23 products because Plaintiff fails to assert any claims of injury or illness as a result of  
24 the use of the products.

### 25 **FIFTH AFFIRMATIVE DEFENSE**

26 The relief sought in the Amended Complaint is barred as a violation of the  
27 Administrative Procedure Act, in that Plaintiff has failed to finalize regulations,  
28 including FDA monographs, related to the Zylast products; Plaintiff has arbitrarily



1 enforced the Act and its regulations against Defendants; Plaintiff has been unduly  
 2 influenced by one of IBD's biggest competitors; Plaintiff failed to properly investigate  
 3 IBD's products; and Plaintiff's regulations, including FDA monographs, are  
 4 impermissibly vague and do not provide adequate notice to Defendant Barough of  
 5 what product statements are permitted and what is forbidden.

6  
 7  
 8 Dated: June 19, 2019

MILLER & CHEVALIER CHARTERED  
 KIRBY D. BEHRE

9  
 10  
 11 By: /s/ Kirby D. Behre  
 KIRBY D. BEHRE  
 Attorneys for Defendants

12  
 13 Benjamin A. Nix (SBN  
 14 138258)  
 Payne & Fears LLP  
 15 Jamboree Center  
 4 Park Plaza, Suite  
 16 1100  
 Irvine, CA 92614  
 Tel.: 949-851-1100  
 17 Fax: 949-851-  
 18 1212  
 Email:  
 19 ban@paynefears.com

Marc C. Sanchez  
 (Admitted *pro hac vice*)  
 Contract In-House  
 Counsel & Consultants  
 LLC (d/b/a FDA Atty)  
 1717 Pennsylvania Ave.  
 NW, Suite 1025  
 Washington, DC 20006  
 Tel.: 202-765-4491  
 Fax.: None  
 Email:  
 msanchez@fdaatty.com

Kirby D. Behre (Admitted  
*pro hac vice*)  
 Email: kbehre@milchev.com  
 Nina C. Gupta (Admitted *pro*  
*hac vice*)  
 Email: ngupta@milchev.com  
 Dwight B.N. Pope (Admitted  
*pro hac vice*)  
 Email: dpope@milchev.com  
 Miller & Chevalier Chartered  
 900 Sixteenth St. NW  
 Washington, DC 20006  
 Tel.: 202-626-5800  
 Fax.: 202-626-5801

20  
 21 *Attorneys for Defendant*  
 22 *HOTAN BAROUGH*  
 23  
 24  
 25  
 26  
 27  
 28



**CERTIFICATE OF SERVICE**

I hereby certify that on June 19, 2019, I electronically filed the foregoing with the Clerk of Court using the CM/ECF System, which will send notice of such filing to the following registered CM/ECF users:

Douglas Ross  
US Department of Justice  
450 Fifth Street NW Suite 6400 South  
Washington, DC 20530  
Email: [douglas.ross2@usdoj.gov](mailto:douglas.ross2@usdoj.gov)

*Counsel for Plaintiff*

/s/ Kirby D. Behre  
Kirby D. Behre (Admitted *pro hac vice*)  
Email: [kbehre@milchev.com](mailto:kbehre@milchev.com)  
Miller & Chevalier Chartered  
900 Sixteenth St. NW  
Washington, DC 20006  
Tel.: 202-626-5800  
Fax.: 202-626-5801

*Attorneys for Defendant*  
**HOTAN BAROUGH**